K053500

FEB 3 2006

510(k) Summary of Safety and Effectiveness for Frameless Radiosurgery Components

Manufacturer:

Address: BrainLAB AG
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85551 Heimstetten
Germany
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Contact Person: Mr. Rainer Birkenbach

Summary Date: January 12, 2006

Device Name:

Trade name: Frameless Radiosurgery System

Common/Classification Name: Frameless Radiosurgery Components

Predicate Device: BrainLAB Mask System (K945903)
BrainLAB CT/X-Ray Localizer (K954861)

Device Classification Name: Medical charged-particle radiation therapy system (892.5050)

Regulatory Class: Class II

Intended Use:
The Frameless Radiosurgery Components are a device used for fixation, localization and repositioning of the patient's

- head and neck
- head, neck, and shoulders

in a linear accelerator environment for stereotactic radiosurgery/radiotherapy procedures.

Device Description:
The Frameless Radiosurgery Components only include mechanical devices, which can be repeatedly attached to the patient to keep his/her head and neck (head, neck and shoulders) in the same position for radiotherapy/radiosurgery. All components are intended to be non-invasive. The Frameless Radiosurgery Components are indicated for any medical condition in which the use of stereotactic radiotherapy may be considered to be safe and effective. They may be used also for repeated diagnostic tomographic scanning. The Frameless Radiosurgery Components can be used with other devices, which have already been cleared by the FDA (e.g. BrainLAB Robotics, BrainLAB Brainscan).

Substantial equivalence:
The Frameless Radiosurgery Components have been verified and validated according to BrainLAB's procedures for product design and development. The validation proves the safety and effectiveness of the system. The information provided by BrainLAB in this 510(k) application was found to be substantially equivalent with the predicate device BrainLAB Mask System (K945903) and BrainLAB CT/X-Ray Localizer (K954861).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2006

Mr. Rainer Birkenbach
Executive Vice President
BrainLAB AG
Ammerthalstraße 8
85551 Heimstetten
GERMANY

Re: K053500
Trade/Device Name: Frameless Radiosurgery Components
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: December 7, 2005
Received: December 16, 2005

Dear Mr. Birkenbach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053500

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Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053500

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)